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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,540	08/18/2000	Dr. Santosh Misra	2847-54358	6802

7590 05/27/2003

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EXAMINER
STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/27/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/641,540	MISRA, DR. SANTOSH	
	Examiner	Art Unit	
	Teresa E Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-16,19-21,30-33,48 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-16,19-21,30-33,48 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Office action is in response to an amendment filed on February 12, 2003. Applicant also filed a declaration under 35 U.S.C. 1.132.

2. Claims 1, 7-16, 19-21, 30-37, 39-48 and 52-54 were pending. Applicant amended claim 1 and canceled claims 34-37, 39-47, 52 and 53. Claims 1, 7-16, 19-21, 30-33, 48 and 54 are pending and will be examined.

3. This Office action contains new grounds for rejection, therefore it is made non-final.

4. Applicant's arguments and the declaration submitted by Dr. Milan Osusky were considered, but were not found persuasive, therefore claims 1, 7-16, 19-21, 30-33, 48 and 54 remain rejected under 35 U.S.C. first paragraph, written description and enablement (see response to arguments).

Response to Arguments

5. Applicant's arguments filed on February 12, 2003 have been fully considered but they are not persuasive.

Applicant argues that the claimed invention, namely, a fragment of a Douglas-fir promoter capable of driving expression of a transgene linked to the fragment in any plant has been described and enabled, since the methods of creating variants of the promoter are described in the specification. Applicant states that examiner stated that the sequence comprising bases 398-853 of SEQ ID NO: 17 was enabled, which is not quite correct, since the exact statement was that this fragment is enabled as a promoter in Douglas-fir only (see line 3 of the second paragraph on page 5). Applicant's own statement in the specification (page 21, lines 11-21) indicates that expression of GUS in tobacco plants driven by the four promoter constructs was very low or non-existent in seeds, embryos, endosperms, leaves and roots (lines 16-20). Applicant concludes with the following statement "However, it is likely that by modifying the promoter structure transcription

activity will be increased.". Applicant has not provided any guidance how to change the promoter structure in order to increase the expression in tobacco plants.

The declaration provided by Dr. Osusky supports the above cited paragraph from the specification in that very little GUS activity is seen when the full-length promoter is used (SEQ ID NO: 17) and the activity is practically non-existent for the other three constructs.

Rejections are maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 7-16, 19-21, 30-32, 48 and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes a promoter with SEQ ID NO: 17 (853 base pairs, which is present in a pMTP0.9 construct) with a sequence obtained from Douglas fir, and fragments of 187 bp (bases 667-853 of SEQ ID NO: 17, which are present in a pMTP0.2 construct), of 456 bp (bases 398-853 of SEQ ID NO: 17, which are present in a pMTP0.5 construct) and of 674 bp (bases 180-853 of SEQ ID NO: 17, which are present in a pMTP0.7 construct). Constructs comprising these sequences fused to the GUS sequence were shown to have promoter activity in Douglas-fir seeds only, but not in any other plants. Expression of these constructs was tested in tobacco plants, but little or no expression of GUS was obtained, indicating that the promoters did not work (page 21,

lines 11-21). The smallest fragment working as a promoter in Douglas fir cells had 187 bp. Therefore, the Applicant did not show that:

1) SEQ ID NO: 17 and the three tested fragments function as promoters in any plant other than Douglas-fir (claims 14, 16, 30-32),

2) SEQ ID NO: 17 and the three tested fragments function as promoters in cells from organisms other than plants and Douglas-fir (claim 15),

3) SEQ ID NO: 17 and the three tested fragments function as inducible promoters (induced by ethylene or a metal) (claim 20),

4) SEQ ID NO: 17 and the three tested fragments function as promoters in gametophytic tissues (claim 21).

The Applicant did not provide a construct between a promoter of SEQ ID NO: 17 and at least one ORF operably linked to the promoter, a vector or a plant cell comprising the construct (claims 10-12) or construct between a promoter of SEQ ID NO: 17 and cationic peptide (claim 13).

The Applicant did not provide any examples or guidance related to making changes in the promoter of SEQ ID NO: 17 or its three tested fragments to obtain a promoter functional in tobacco or plants other than Douglas-fir.

8. Claims 1, 7-16, 19-21, 30-32, 48 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter comprising SEQ ID NO: 17 and nucleotides 667-853, 398-853 and 180-853 of SEQ ID NO: 17 and functional in Douglas-fir, does not reasonably provide enablement for a promoter comprising SEQ ID NO: 17 and nucleotides 667-853, 398-853 and 180-853 of SEQ ID NO: 17 being functional in any cells other than Douglas-fir. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification describes a promoter with SEQ ID NO: 17 (853 base pairs, which is present in a pMTP0.9 construct) with a sequence obtained from Douglas fir, and fragments of 187 bp (bases 667-853 of SEQ ID NO: 17, which are present in a pMTP0.2 construct), of 456 bp (bases 398-853 of SEQ ID NO: 17, which are present in a pMTP0.5 construct) and of 674 bp (bases 180-853 of SEQ ID NO: 17, which are present in a pMTP0.7 construct). Constructs comprising these sequences fused to the GUS sequence were shown to have promoter activity in Douglas-fir seeds only, but not in any other plants. Expression of these constructs was tested in tobacco plants, but little or no expression of GUS was obtained, indicating that the promoters did not work (page 21, lines 11-21). The smallest fragment working as a promoter in Douglas fir cells had 187 bp. Therefore, the Applicant did not show that:

1) SEQ ID NO: 17 and the three tested fragments function as promoters in any plant other than Douglas-fir (claims 14, 16, 30-32),

2) SEQ ID NO: 17 and the three tested fragments function as promoters in cells from organisms other than plants and Douglas-fir (claim 15),

3) SEQ ID NO: 17 and the three tested fragments function as inducible promoters (induced by ethylene or a metal) (claim 20),

4) SEQ ID NO: 17 and the three tested fragments function as promoters in gametophytic tissues (claim 21).

The Applicant did not provide a construct between a promoter of SEQ ID NO: 17 and at least one ORF operably linked to the promoter, a vector or a plant cell comprising the construct (claims 10-12) or construct between a promoter of SEQ ID NO: 17 and cationic peptide (claim 13).

The Applicant did not provide any examples or guidance related to making changes in the promoter of SEQ ID NO: 17 or its three tested fragments to obtain a promoter functional in tobacco or plants other than Douglas-fir.

The Applicant described a modular structure of the promoter of SEQ ID NO: 17, with the smallest fragment functional as a promoter being nucleotides 667-853 of SEQ ID NO: 17. The promoter modules in a lot of cases require a precise spacing of the modules for functionality, therefore it is critical to determine which nucleotide fragments constitute functional promoter modules (see Vetten et al., Int. J. Biochem., vol. 9, pp. 1055-1068, 1994).

Due to the large quantity of experimentation necessary to determine how to modify SEQ ID NO: 17 or its three fragments to function as promoters in any host cell, the lack of direction/guidance presented in the specification regarding modification of SEQ ID NO: 17 or its three fragments to make them functional as promoters in any host cell, the absence of working examples directed to modification of SEQ ID NO: 17 or its three fragments to make them functional as promoters in any host cell, the complex nature of the invention, the unpredictability of changes in the promoter sequence on its function due to modular structure of plant promoters (see reference above), undue experimentation would be required of the skilled artisan to make and use claimed invention in its full scope.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

10. Claims 1, 7-12, 14-16, 19-21, 30, 33, 48 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Chatthai (Ph. D. Dissertation, University of Victoria, June 1999).

Regarding claims 1, 7, 10, 48 and 54, Chatthai teaches a recombinant promoter of SEQ ID NO: 17 in a vector construct pMTP0.9 with GUS, nucleotides 398-853 of SEQ ID NO: 17 in a vector construct pMTP0.5 with GUS and nucleotides 180-853 of SEQ ID NO: 17 in a vector construct pMTP0.7 with GUS (Fig. 32, page 136; page 149, 150; Figure 41, 42).

Regarding claims 8, 12, 14-16, 19, 21 and 33, Chatthai teaches that the vectors were introduced into cells of Douglas-fir stage 6 megagemetophyte, stage 6 zygotic embryos and mature somatic embryos and the GUS protein was expressed in these cells (page 150).

Regarding claims 9 and 30, Chatthai teaches tobacco plants transformed with the vectors containing the four promoter constructs (page 151, second paragraph).

Regarding claim 20, Chatthai teaches transcriptional activation of the PM2.1 gene in response to metal ions, such as iron, copper, manganese and zinc (page 177, third paragraph).

11. Claims 1, 7-12, 14-16, 19-21, 30, 33, 48 and 54 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Applicant's disclosure appears to be identical to a Ph. D. dissertation of Malinee Chatthai, entitled "Molecular characterization and regulation of embryogenesis-associated genes in Duglas-fir (Pseudotsuga menziesii [Mirb.] Franco)", defended at the Department of Biochemistry and Microbiology of the University of Victoria, Canada. Graduate degrees, in particular Ph. D.s, are based on independent research projects. Accordingly, Chatthai anticipates the claimed invention. In response to this rejection Applicant should clearly state the inventive contribution of Chatthai, if any, to the claimed invention.

12. No references were found teaching or suggesting claims 13, 31 and 32 but they are rejected for reasons given above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

May 18, 2003

Teresa Strzelecka, Ph. D.

Patent Examiner

Teresa Strzelecka
5/18/03